

At page 1, line 19: Please delete "filed on \_\_\_\_\_" and substitute --filed on January 9, 1997-- therefor.

At page 1, line 21: Please delete "Serial No. \_\_\_\_\_" and substitute --Serial No. 08/781,577-- therefor.

At page 1, line 23: Please delete "filed on \_\_\_\_\_" and substitute --filed on January 9, 1997-- therefor.

At page 11, lines 22: Please delete "a tissue and synthetic graft" and substitute --a tissue and graft-- therefor.

L At page 11, immediately following line 23: Please add the following sentence: -As

Al used herein, the term "tissue" may refer to any vascular passage or other body organ, and the term "graft" may refer to any biological or synthetic graft. -

At page 17, line 5: Please delete "Serial No. \_\_\_\_\_" and substitute --Serial No. 08/781,578-- therefor.

At page 33, line 20: Please delete "Serial No. \_\_\_\_\_" and substitute --Serial No. 08/781,578-- therefor.

At page 36, line 16: Please delete "Serial No. \_\_\_\_\_" and substitute --Serial No. 08/781,577-- therefor.

In the Claims,

Please amend Claims 1-6, 8-13, 15, 16, 18, 19 and 23.

Please cancel Claims 17, 20, 24 and 25.

Please add new Claims 26-66.

The claims have been reproduced in full below for convenience.

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1. (Once Amended) A surgical [staple] fastener comprising:  
a base having at least one substantially planar surface,  
a flange bendably joined to [one] a first edge of the base and having at least  
one substantially planar surface adapted to cooperate with the planar surface of the base,  
a pin bendably joined to the base at a second edge of said base [an] opposing  
the first edge, and  
a needle for skewering tissues, or tissue and graft, the needle being  
removably joined to the pin to receive the tissues, or tissue and graft, from the needle, the  
pin and flange capable of bending over the base to fix the tissues, or tissue and graft,  
together. [and comprising a suture needle, wherein the base and the flange each have  
cooperating surfaces to contact and secure on the pin portions of tissues to be joined  
together or portions of a graft to an artery.]

2. (Once Amended) A surgical [staple] fastener defined in claim 1 wherein  
the base is configured to be releasably engaged with an associated applying instrument.

3. (Once Amended) A surgical [staple] fastener for securing portions of  
tissues, or tissue and graft, together [or portions of a graft to a tissue] comprising:

base means having at least one substantially planar surface [for securing  
tissues or grafts],

flange means bendably joined to [one] a first edge of the base means and  
having at least one substantially planar surface for cooperating with the planar surface of  
the base means [to secure tissues or grafts],

pin means bendably joined to the base means at a second edge of said base  
[an] opposing the first edge [for holding tissues or grafts], and  
needle means removably joined to the pin means for piercing tissues, or  
tissue and graft. [or grafts and comprising a suture needle], wherein the base means and the  
flange means each have cooperating surfaces to contact and secure on the pin means  
portions of tissues, or tissue and graft, to be joined together [or portions of a graft to an  
artery].

4. (Once Amended) A surgical [staple] ~~fastener~~ defined in claim 3 wherein  
the base means includes means for releasably engaging an associated applying instrument.

5. (Once Amended) An instrument for applying a surgical staple  
comprising:  
an elongated shaft having a distal end portion,  
a staple holder [member] at the distal end portion adapted to engage a staple  
and a needle removably joined to the staple, the staple having a base [having] including at  
least one substantially planar surface, a flange bendably joined to [one] a first edge of the  
base and having at least one substantially planar surface adapted to cooperate with the  
planar surface of the base, and a pin bendably joined to an edge of the base [at an]  
opposing said first edge], and a needle removably joined to the pin, and comprising a  
suture needle],

a staple forming member at the distal end portion adapted to bend the pin over a substantial portion of the base and to bend the flange over a substantial portion of the pin, so that the staple is substantially closed, and

a handle having a control for actuating the staple forming member.

6. (Once Amended) An instrument defined in claim 5 wherein the elongated shaft has a length and width adapted [to] for use in minimally invasive surgery.

7. An instrument as defined in claim 5 wherein the base is configured to be releasably engaged by the staple holder, and the handle has a control for releasing the staple after it is closed.

8. (Once Amended) An instrument as defined in claim 5 wherein the staple holder [member] is also adapted to articulate the [staple] needle relative to the elongated shaft, and the handle has a control for actuating an articulating mechanism.

9. (Once Amended) An instrument as defined in claim 5 wherein the instrument further comprises a needle removal member at the distal end portion adapted to remove the needle from the [pin] staple.

10. (Once Amended) An instrument as defined in claim 5 wherein:

[the staple holder member contains at least one staple comprising a base having at least one substantially planar surface, a flange bendably joined to one edge of the base and having at least one substantially planar surface adapted to cooperate with the planar surface of the base, a pin bendably or rotatably joined to the base at an opposing edge, and a needle joined to the pin and comprising a suture needle, wherein] the base and the flange each have cooperating surfaces to contact and secure on the pin portions of tissues to be joined or portions of a graft to an artery.

11. (Once Amended) An instrument as defined in claim 10 wherein the elongated shaft [comprising at its distal end portion a staple] has a maximum diameter less than about 20 millimeters.

12. (Once Amended) An instrument for applying a surgical staple comprising:

an elongated shaft having a distal-end portion,  
staple holder means at the distal end portion for holding a staple and a needle  
removably attached to the staple for piercing tissues, or tissue and graft, the staple  
comprising base means having at least one substantially planar surface for securing tissues  
or grafts, flange means bendably joined to one edge of the base means and having at least  
one substantially planar surface for cooperating with the planar surface of the base means to  
secure tissues or grafts, and pin means bendably joined to the base means at an opposing  
edge for holding tissues or grafts, [and needle means removably joined to the pin means for

piercing tissues or grafts and comprising a suture needle,] wherein the base means and the flange means each have cooperating surfaces to contact and secure on the pin means portions of tissues to be joined together or portions of a graft to an artery,

staple forming means associated with the staple holder means for bending the pin means over a portion of the base means, and for folding the flange means over a substantial portion of the pin means so that the staple is substantially closed, and a handle having control means for actuating the staple forming means.

13. (Once Amended) An instrument defined in claim 12 wherein the elongated shaft has a length and width adapted [to] for use in minimally invasive surgery.

14. An instrument as defined in claim 12 wherein the base means includes means for releasably engaging the staple holder means, and the handle has control means for releasing the staple after it is closed.

15. (Once Amended) An instrument as defined in claim 12 wherein the staple holder means includes means to articulate the [staple] needle relative to the elongated shaft, and the handle has control means for actuating such articulation means.

16. (Once Amended) An instrument as defined in claim 12 wherein the instrument further comprises needle removal means at the distal end portion for removing the needle from the pin means.

[

17. An instrument as defined in claim 12 wherein:

the staple holder means contains at least one staple comprising base means having at least one substantially planar surface for securing tissues or grafts, flange means bendably joined to one edge of the base means and having at least one substantially planar surface for cooperating with the planar surface of the base means to secure tissues or grafts, pin means bendably joined to the base means at an opposing edge for holding tissues or grafts, and needle means removably joined to the pin means for piercing tissues or grafts and comprising a suture needle,

wherein the base means and the flange means each have cooperating surfaces to contact and secure on the pin means portions of tissues to be joined or portions of a graft to an artery.]

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18. (Once Amended) An instrument as defined in claim [17] 12 wherein the

elongated shaft [comprising at its distal end portion a staple] has a maximum diameter less than about 20 millimeters.

*A2*  
19. (Once Amended) A method for attaching soft tissues located in the abdominal cavity, chest and retroperitoneal space and for attaching a graft to an artery in these areas comprising:

providing an instrument for applying a surgical staple having an elongated shaft with a distal end portion and having a staple forming member at the distal end portion adapted to bend portions of a staple,

providing [at least one staple to] a staple holder [member] at the distal end of the instrument with at least one staple, and a needle attached to each at least one staple, the at least one staple comprising a base having at least one substantially planar surface, a flange bendably joined to one edge of the base and having at least one substantially planar surface adapted to cooperate with the planar surface of the base, and a pin bendably joined to the base at an opposing edge, [and a needle removably joined to the pin and comprising a suture needle,] wherein the base and the flange each have cooperating surfaces to contact and secure on the pin portions of tissues to be joined together or portions of a graft to an artery[.] .

incising a patient's tissue to create at least one opening into the patient's abdominal cavity, chest or retroperitoneal space,

inserting the distal end of the instrument through the opening, so that the distal end is disposed in the patient,

passing the needle [of the staple] through a portion of one tissue, graft or artery and through a portion of a second tissue, artery or graft, and

actuating the staple forming member to bend the pin over a substantial portion of the base and to bend the flange over a substantial portion of the pin, so that the staple is substantially closed.

[ 20. The method defined in claim 19 wherein the method further comprises providing a staple further comprising a the base is configured to be releasably engaged by the staple holder and releasing the staple from the instrument.]

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*B3R*

21. The method defined in claim 19 wherein the passing and actuating steps are repeated to apply additional staples.

*A3*

22. The method defined in claim 19 wherein the incising step creates a small incision and wherein the inserting, passing and actuating steps are performed by minimally invasive surgical procedures.

23. (Once Amended) The method defined in claim 19 wherein the shaft of the needle [member] is passed through a portion of a first graft or artery and through a second [an] artery or graft to form a portion of an artery to graft anastomosis.

[ 24. The method defined in claim 19 wherein the artery is selected from the group consisting of the aorta, the coronary arteries, the iliac arteries and the femoral arteries.]

[ 25. The method defined in claim 24 wherein the artery is at least about 2 mm diameter or larger. ]

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26. (New) A surgical staple system for fastening together tissues, or tissue and graft, comprising:

a first section adapted to be removably joined to a tissue and/or graft piercing implement; and

a second section adjacent to said first section and adapted to be releasably gripped by a staple applying instrument, said first and second sections capable of moving from a first orientation, where portions of said first and second sections are spaced apart sufficiently to receive the tissues, or tissue and graft, therebetween, to a second orientation, where said first and second sections lie in contact with the tissues, or tissue and graft.

27. (New) A surgical staple as recited in claim 26, further comprising a third section adjacent to said second section, said third section capable of being bent with respect to said second section.

28. (New) A surgical staple as recited in claim 26, further comprising a piercing implement removably joined to said first section.

29. (New) A surgical staple system for fastening tissues, or tissue and graft, together, comprising:

a base having a substantially planar surface and adapted to be releasably gripped by a staple applying instrument;

a flange having a substantially planar surface attached to a first edge of said base, said flange capable of moving from a first position, where said substantially planar surfaces of said flange and base are spaced apart sufficiently to receive the tissues, or tissue and graft, therebetween, to a second position, where said substantially planar surfaces of said base and flange lie in contact with the tissues, or tissue and graft; and

a pin attached to a second edge of said base different from said first edge, said pin adapted to releasably join with a needle, said pin capable of moving from a first position, where said pin and said substantially planar surface of said base are spaced apart sufficiently to receive the tissues, or tissue and graft, therebetween, to a second position, where said pin and said substantially planar surface of said base lie in contact with the tissues, or tissue and graft.

30. (New) A surgical staple system as recited in claim 29 further comprising a needle releasably joined to said pin.

31. (New) A surgical staple system for fastening tissues, or tissue and graft, together, comprising:

a staple including at least a first section adjacent to a second section, said first and second sections capable of moving from a first orientation, where said first and second sections are spaced apart sufficiently to receive the tissues, or tissue and graft, therebetween, to a second orientation, where said first and second sections lie in contact with the tissues, or tissue and graft; and

a needle capable of aligning and skewering the tissues, or tissue and graft, said needle removably attached to one of said first or second sections of said staple.

32. (New) A surgical fastening system, comprising:

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a needle including a first end capable of passing through tissue, or tissue and graft, and a second end opposite said first end; and

an instrument capable of manipulating said needle in a minimally invasive procedure such that said needle skewers a first tissue or graft onto said needle, aligns said first tissue or graft to a desired position with respect to a second tissue or graft, and skewers said second tissue or graft on said needle.

33. (New) A surgical fastener system as recited in claim 31, further comprising manual controls for controlling said instrument.

34. (New) A surgical fastener system as recited in claim 31, further comprising automated robotic controls for controlling said instrument.

35. (New) A surgical fastener system as recited in claim 31, further comprising a staple removably attached to said needle, said staple capable of fastening said first tissue or graft to said second tissue or graft.

36. (New) A surgical fastener system, comprising:  
a staple including at least first and second joined sections;  
a needle affixed to an end of one section of said at least first and second joined sections;  
an instrument capable of manipulating said needle in a minimally invasive procedure such that said needle skewers a first tissue or graft, aligns said first tissue or graft to a desired position with respect to a second tissue or graft, and skewers said second tissue or graft, and said instrument capable of folding said at least first and second joined sections

with respect to each other to secure said first tissue or graft to said second tissue or graft between said at least first and second joined sections of the staple.

37. (New) A surgical staple system comprising:
- a staple including first, second and third sections;
  - a needle affixed to said first section; and
  - an instrument, including:
    - a proximal end,
    - a distal end opposite said proximal end, said distal end including first means for manipulating said needle in a minimally invasive procedure such that said needle skewers tissues, or tissue and graft, onto said first section, and second means for folding said first and third sections with respect to said second section,
    - means for operatively connecting said proximal and distal ends, and
    - at least one hand-actuated mechanism in said proximal end for controlling said first means for manipulating said needle and said second means for folding said first and third sections with respect to said second section.

38. (New) A surgical staple system as recited in claim 37, further comprising third means in said distal end for removing said needle from said first section.

39. (New) A surgical staple system as recited in claim 38, wherein said second means for folding said first and third sections with respect to said second section and said third means for removing said needle from said first section retract proximally

from said distal end to provide a clear line of sight for a surgeon to the needle while said first means manipulates said needle.

40. (New) A surgical staple system as recited in claim 37, wherein said means for operatively connecting said proximal and distal ends comprises drive rods connected between said hand-actuated mechanisms and said first means for manipulating said needle and said second means for folding said first and third sections with respect to said second section.

41. (New) A surgical staple system comprising:

a staple including first, second and third sections;

a needle affixed to said first section; and

an instrument, including:

a proximal end,

a distal end opposite said proximal end, said distal end including first means for manipulating said needle in a minimally invasive procedure such that said needle skewers tissues, or tissue and graft, onto said first section, and second means for folding said first and third sections with respect to said second section,

means for operatively connecting said proximal and distal ends, and

at least one automated robotic mechanism in said proximal end for controlling said first means for manipulating said needle and said second means for folding said first and third sections with respect to said second section.

42. (New) A surgical staple system as recited in claim 41, wherein said means for operatively connecting said proximal and distal ends comprises drive rods connected between said automated robotic mechanism and 1) said first means for manipulating said needle, and 2) said second means for folding said first and third sections with respect to said second section.

43. (New) A surgical staple system for fastening tissues, or tissue and graft, together, comprising:

a staple including a first section joined to a second section; and  
an instrument having a proximal and distal end, including:  
means in said distal end for holding said staple,  
means in said distal end for articulating said staple,  
means in said distal end for bending said first section with respect to  
said second section in a minimally invasive procedure,  
controls located remotely from said distal end for actuating said  
staple holding means, said staple articulating means, and said bending means, and  
connecting means for connecting said controls in the proximal end  
with the staple holding means, said staple articulating means, and said bending  
means in said distal end.

44. (New) A surgical staple system as recited in claim 43, further comprising a needle affixed to said staple for skewering the tissues, or tissue and graft, and for locating the tissues, or tissue and graft, in a desired position with respect to the staple.

45. (New) A surgical staple system as recited in claim 44, wherein said needle is articulated by said means for articulating said staple.

46. (New) A surgical staple system as recited in claim 45, further comprising means for removing said needle from said staple.

47. (New) A surgical staple system as recited in claim 46, wherein means for bending said first section with respect to said second section and said means for removing said needle from said staple retract proximally from said distal end to provide a clear line of sight for a surgeon to said needle while said means for articulating said staple articulates said needle.

48. (New) An instrument including distal and proximal ends for fastening tissues, or tissue and graft, together with a staple in a minimally invasive surgical procedure, the staple including a base, a flange attached to a first edge of said base, and a pin attached to an edge of said base other than the first edge, the pin having a needle removably mounted thereon for skewering the tissues, or tissue and graft, comprising:  
a staple holder in the distal end for holding the staple and needle;  
means in the distal end for articulating said staple holder, to manipulate the needle such that the needle skewers the tissues, or tissue and graft, on the needle in a desired position with respect to each other, and positions the tissues, or tissue and graft, on the pin;  
means in the distal end for removing the needle from the staple;

a staple forming member in the distal end, including:

means for bending the pin down over the base, and

means for bending the flange down over the pin and base;

controls located remotely from said distal end for actuating said means for articulating said staple holder, said means for removing the needle, and said staple forming member; and

connecting means spanning between the distal and proximal ends of the instrument for connecting said controls to said means for articulating said staple holder, said means for removing the needle, and said staple forming member.

49. (New) An instrument including distal and proximal ends for fastening tissues, or tissue and graft, together as recited in claim 48, wherein said means for removing the needle from the staple and said staple forming member retract proximally from said distal end to provide a clear line of sight for a surgeon to said needle while said means for articulating said staple holder manipulates said needle.

50. (New) An instrument including distal and proximal ends for fastening tissues, or tissue and graft, together as recited in claim 48, wherein said controls comprise hand-actuated controls.

51. (New) An instrument including distal and proximal ends for fastening tissues, or tissue and graft, together as recited in claim 48, wherein said controls comprise automated robotic controls.

52. (New) An instrument including distal and proximal ends for fastening tissues, or tissue and graft, together as recited in claim 48, wherein said controls and said connecting means together comprise an automated robotic system for actuating said means for articulating said staple holder, said means for removing the needle, and said staple forming member.

53. (New) An instrument including distal and proximal ends for fastening tissues, or tissue and graft, together as recited in claim 48, further comprising a motor, controlled by said controls, for actuating said connecting means.

54. (New) An instrument including distal and proximal ends for fastening tissues, or tissue and graft, together as recited in claim 48, further comprising pneumatic means, controlled by said controls, for actuating said connecting means.

55. (New) An instrument including distal and proximal ends for fastening tissues, or tissue and graft, together as recited in claim 48, further comprising hydraulic means, controlled by said controls, for actuating said connecting means.

56. (New) A method of fastening together tissues, or tissue and graft, in a minimally invasive procedure, comprising the steps of:

- (a) delivering a distal end of an endoscopic instrument through an incision in the outer body wall to a site where a first tissue or graft is to be fastened to a second tissue or graft; and

(b) sewing the first tissue or graft to the second tissue or graft with the endoscopic instrument.

57. (New) A method of fastening together tissues, or tissue and graft, as recited in claim 56, further comprising a step (c) of fastening together the first tissue or graft to the second tissue or graft sewn together in said step (b) with a staple provided on the distal end of the instrument.

58. (New) A method of fastening together tissues, or tissue and graft, in a minimally invasive procedure, comprising the steps of:

- (a) skewering a first tissue or graft onto a needle held by an instrument in a minimally invasive procedure;
- (b) aligning the first tissue or graft skewered on the needle in said step (a) to a desired apposition with respect to a second tissue or graft in a minimally invasive procedure; and
- (c) skewering the second tissue or graft onto the needle in the desired apposition identified in said step (b) in a minimally invasive procedure.

59. (New) A method of fastening together tissues, or tissue and graft, as recited in claim 58, further comprising a step (d) of fastening the first tissue or graft to the second tissue or graft in the desired position with respect to each other identified in said step (b).

60. (New) A method of fastening together tissues, or tissue and graft, as recited in claim 59, further comprising the step (e) of removing the needle from the instrument and first and second tissues or grafts prior to said step (d) of fastening the first and second tissues or grafts together.

61. (New) A method of fastening together a first tissue or graft and a second tissue or graft in a minimally invasive procedure by a fastener including at least first and second joined sections, comprising the steps of:

(a) positioning the first tissue or graft and the second tissue or graft in a desired relation to each other on one section of the fastener in a minimally invasive procedure; and

(b) folding the at least first and second sections of the fastener with respect to each other in a minimally invasive procedure to trap and fasten together the first tissue or graft and the second tissue or graft between the at least first and second sections of the fastener.

62. (New) A method of fastening together a first tissue or graft and a second tissue or graft as recited in claim 61, wherein said step (b) of folding the at least first and second sections of the fastener with respect to each other comprises the steps of:

(c) folding the one section of the fastener with the first and second tissues or grafts positioned thereon down over a second section of the fastener; and

(d) folding a third section of the fastener down over said first and second sections of the fastener.

63. (New) A method of fastening together a first tissue or graft and a second tissue or graft by a fastening system including a fastener having at least first and second joined sections and a section adapted to pierce tissues and/or grafts, and an instrument for applying the fastener in a minimally invasive procedure, comprising the steps of:

- (a) delivering the fastener to the site where the first tissue or graft is to be fastened to the second tissue or graft by the instrument through an incision in the outer body wall;
- (b) skewering the first tissue or graft onto a section of the fastener in a minimally invasive procedure;
- (c) aligning the first tissue or graft skewered on the fastener in said step (b) in a desired position to the second tissue or graft in a minimally invasive procedure;
- (d) skewering the second tissue or graft onto a section of the fastener in a minimally invasive procedure; and
- (e) folding the at least first and second sections of the fastener with respect to each other in a minimally invasive procedure to trap and fasten together the first tissue or graft and the second tissue or graft between the at least first and second sections of the fastener.

64. (New) A method of fastening together a first tissue or graft and a second tissue or graft as recited in claim 63, wherein said step (e) of folding the at least first and second sections of the fastener with respect to each other comprises the steps of:

- (f) folding the one section of the fastener with the first and second tissues or grafts positioned thereon down over a second section of the fastener; and
- (g) folding a third section of the fastener down over said first and second sections of the fastener.

65. (New) A method of fastening together a first tissue or graft and a second tissue or graft as recited in claim 63, wherein said step (b) of skewering the first tissue or graft onto a section of the fastener and said step (d) of skewering the second tissue or graft onto a section of the fastener comprises the steps of:

- (f) skewering the first and second tissues or grafts onto the section of the fastener adapted to pierce the first and second tissues or grafts; and
- (g) moving the first and second tissues or grafts onto a section of the fastener adjacent to the section of the fastener adapted to pierce tissues.

66. (New) A method of fastening together a first tissue or graft and a second tissue or graft as recited in claim 65, further comprising the step (h) of removing the section of the fastener adapted to pierce tissues or grafts from the fastener.